

REMARKS

Present Status of the Application

Claims 32-70 remain pending and claims 32-36, 38-41 and 45-49 were examined, along with elected species a) linseed oil for claims 32-36 and 38, b) palmitic acid for claims 40-41 and c) paclitaxel for claims 45-48.

The First Office Action dated May 11, 2009 objected the abstract for informalities. Claims 40-41 & 45-48 were rejected under 35 USC 112, second paragraph as being indefinite. Claims 56-60 & 65-70 were incomplete as being dependent on cancelled claims. Claims 32-36, 38-39 and 45-47 were rejected under 35 USC 102(b) as being anticipated by Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113). Claim 48 was rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113). Claims 40-41 were rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113) in view of Kashiwagi et al. (USP 5,336,698). Claim 49 was rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113) in view of Kashiwagi et al. (USP 5,336,698) and Smeds et al. (J. of Biomedical Material Research, 54, 114-121 (2001)).

Claims 32, 40, 45 and 58 have been amended to provide more descriptions for

clarification and for correcting dependency. New dependent claim 71 has been added. Claims 37, 42-44, 49, 56-57 and 65-70 have been cancelled. The abstract have been amended for correcting informalities and for clarification purposes. It is believed that the amendments are supported by the original specification and drawings of this application and can overcome the objections. After entering the amendments and considering the following discussions, a notice of allowance is respectfully solicited.

Discussion for the objections

The abstract was objected for informalities.

Accordingly, the terms “said” have been amended as “the”, while the phrase “the same” has been amended as “such medical products” for clarification. In addition, the phrase “not participating in the polymerization” has been added following “substances” in line 7 for clarification.

Entry of the amendments to the abstract is respectfully requested.

Discussion of 112 rejections

Claims 40-41 & 45-48 were rejected under 35 USC 112, second paragraph as being indefinite. Claims 56-60 & 65-70 were incomplete as being dependent on cancelled claims.

Claims 40 and 45 have now been amended to be dependent on newly added dependent claim 71 for proper antecedent basis. Claim 58 has been amended to correct dependency as being dependent on claim 32. Claims 42-44, 56-57 and 65-70 have been cancelled.

Accordingly, withdrawal and reconsideration of these 112 rejections are respectfully requested.

Discussions of 102 and 103 rejections

Claims 32-36, 38-39 and 45-47 were rejected under 35 USC 102(b) as being anticipated by Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113). Claim 48 was rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113). Claims 40-41 were rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113) in view of Kashiwagi et al. (USP 5,336,698). Claim 49 was rejected under 35 USC 103(a) as being unpatentable over Allen-Petit et al. (WO 2003/039612A1), as evidenced by Mallégol et al. (Progress in Organic Coatings, 39 (2000), 107-113) in view of Kashiwagi et al. (USP 5,336,698) and Smeds et al. (J. of Biomedical Material Research, 54, 114-121 (2001)).

At first, according to MPEP 2131, **TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM**

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, **in a single prior art reference.**” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Also in

MPEP 2131.01, III, “To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is **necessarily** present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

CCPA also indicated “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Oelrich*, 666 F. 2d 578, 581, 212 USPQ323, 326 (C.C.P.A. 1981).

So far, the Office Action has not established a reasonable basis for anticipation.

Claim 32 has been amended to recite "the polymerization takes place after coating the surface of the medical product by means of exposure to aerial oxygen and UV light" to provide more descriptions for clarification. Supporting grounds can be found at least in page 4, lines 19 to 22 and page 5, lines 14 to 17 of the English text of the specification for the present application. In addition in example 2 of the present application it is specified that the light used for polymerization is UV radiation or UV light.

Claims 37, 42-44, 49, 56, 57 and 65-70 have been cancelled.

Newly added dependent claim 71 reads as: "Medical product according to claim 32, wherein the substances for the polymer layer further comprises substances not participating in the polymerization reaction.". Supporting grounds of such feature are disclosed at page 16, line 37 to

page 17, line 11 of the description of the present application.

Claims 40 and 45 have now been amended to be dependent on newly added dependent claim 71 for proper antecedent basis. Claim 58 has been amended to correct dependency as being dependent on claim 32.

The reference Allen-Petit, even evidenced by Mallégol fails to disclose each and every features of the medical product of amended claim 32. Hence, the amended claim 32 patentably distinguishes over Allen-Petit or Mallégol.

In fact, neither Allen-Petit nor Mallégol teaches the feature of a polymerization taking place on the surface of a medical product.

The independent claim 32 of the present application contains now the feature "the polymerization takes place after coating the surface of the medical product by means of exposure to aerial oxygen and UV light", which is not taught or suggested by any one of the references mentioned above.

The Office Action considered that Allen-Petit mentioned linseed oil, which was comparable to the substances that participates in the polymerization, and admitted that Allen-Petit fails to teach "linseed oil polymerizes.

As a matter of fact, one of the important objects emphasized by Allen-Petit is "a coating which does not need an aggressive polymerization step" (page 2, lines 5-6). Also, Mallégol merely describes the **possible** mechanism and conditions of polymerization of drying oils.

In step g) of Allen-Petit, it is clearly explained that the prosthesis freshly coated with a solution or emulsion of an oil in an organic solvent is air dried until the organic solvent is

evaporated. Step h) describes that the foregoing coating steps might be repeated several times and step i) states that the freshly coated prosthesis is further air dried in a sterile laminar flow.

Mallégol teaches that the unsaturated molecules of linseed oil can polymerize via an oxidative polymerization mechanism under different sets of polymerization conditions. These polymerization conditions are:

a) aerial oxygen and a temperature below 40°C, completion of polymerization after about 200 hours at for example at 25°C (see page 107, introduction; page 108, scheme 2, way B; page 109, left column, chapter "Results and discussion", 2nd paragraph and figure 1; and page 110, left column, 1st paragraph and figure 3)

b) aerial oxygen and a temperature above 40°C (see page 107, introduction; page 108, scheme 2, way A)

c) aerial oxygen and catalyst, completion of polymerization after about 3 hours at for example 25°C (page 109, left column, chapter "Results and discussion", 2nd paragraph; and page 110, left column, 1st paragraph and figures 2 and 3)

To any one skilled in the field of coating implants with oils, the evaporation of an organic solvent from an oil coating is completed within 5 to 10 minutes. Whereas the polymerization of the oils on the implant surface takes at least several hours even if it is accelerated by heating (see examples of the present application). Without the acceleration by heating the polymerization takes between weeks and months.

The conditions applied by Allen-Petit in step g) correspond to aerial oxygen, temperature below 40°C and duration of these conditions for 5 to 10 minutes. According to Mallégol's

disclosures or common knowledge in this field, polymerization is impossible to occur under the conditions of step g) of Allen-Petit. Even if the coating steps from a) to g) were repeated several times as stated by step h) of Allen-Petit, a polymerization would be impossible. Therefore, a polymerization will be impossible either during step i) or during the whole coating procedure of Allen-Petit.

In the reference Allen-Petit, the adherence is obtained because of the fatty and viscous nature of the fats or oils (see page 3, lines 3-4). Additionally the unsaturated fats or oils are partially hydrogenated to increase their melting point.

According to Allen-Petit, the conditions for coating an implant with fats or oils can be summarized as: use of fats or oils with minimal amount of multiple bonds; contact of the fats and oils to be used for coating with anti-oxidative and/or deoxidative compounds; and minimal contact to aerial oxygen at room temperature.

As discussed above, under these conditions of Allen-Petit, it is not possible to perform a polymerization of the fats or oils on the surface of an implant.

Furthermore the features of using fats or oils for coating with only minimal content of multiple bonds and introducing deoxidative and anti-oxidative compounds in the coating composition of Allen-Petit would lead someone skilled in the art to non-polymerized oil coatings and thus to the opposite direction as compared to the present invention.

In contrast, the conditions applied in the present application for the coating of medical products with oils, namely highly unsaturated oils, contact to oxygen in combination with UV light and preferably no contact to deoxidative or anti-oxidative compounds, are able to produce a

three dimensional polymer network of the oil molecules by polymerization.

In the present application the adherence of the coating onto the implant is obtained by the polymerization of the unsaturated oil molecules. Although the main tasks of the polymer coating are to provide a hemocompatible surface to the implant and generate a slow release of active agent, a positive effect is that the three dimensional polymer network builds a very stable covering on the implant. So by employing polymerization for coating the implant there is no need to worry about the quality of adherence of the coating to the implant.

As stated by Mallégol performing a polymerization of unsaturated oils at temperatures below 40°C needs a polymerization time of weeks. Thus completion of polymerization needs too much time to be applicable for commercial purposes. Also, Mallégol recommended using a metal salt catalyst or a combination of catalysts to significantly reduce the polymerization time of unsaturated oils (see page 107, right column, last paragraph to page 108, left column, first paragraph). But, based on the experiments, the achieved coating was not uniform but presented a puckered surface which poorly adhered to the surface of the medical product. Contacting this coating with buffer or blood for a longer period resulted in detaching of the oil polymer coat from the surface of the medical product (page 112, right column, chapter "Conclusions"). Thus Mallégol's polymerization conditions of aerial oxygen and catalyst did not prove to be suited for generating stable hemocompatible coatings on the surface of the medical product.

Because of the above outlined reasons the present application is regarded as being inventive over Allen-Petit, even if evidenced by Mallégol.

Further, the Office Action rejected claims 40, 41, 48 and 49 for lacking inventive step

over Allen-Petit, Mallégol, Kashiwagi in view of Smeds.

But Kashiwagi fails to remedy the deficiencies as discussed above. Kashiwagi et al. even does not describe a polymerization on the surface of a medical product. The polymers used by Kashiwagi are polymerized prior to applying it to the surface of the medical product. Thus the present invention as represented by the amended claims is also inventive over Kashiwagi.

Even a combination of the teachings of Allen-Petit, Mallégol and Kashiwagi does not disclose nor suggest to coat a medical product via polymerization of unsaturated oils after depositing the oils to the surface of the medical product and by means of exposure to aerial oxygen and UV light. Therefore the present invention as represented by the amended claims is also regarded as being inventive over these references.

Claim 49 has been cancelled. As claim 49 has been cancelled, the reference Smeds is irrelevant.

However, Applicant would like to point out that Smeds merely discloses crosslinking reaction, **rather than polymerization**, initiated by a catalyst and exposure to laser light.

Polymerization is clearly defined as a chemical process in which monomers react with each other to build chain-like or network-like polymer molecules (please refer to <http://en.wikipedia.org/wiki/Polymerization> or <http://www.britannica.com/EBchecked/topic/468745/polymerization>). As explained above, no monomers participate in the surface reactions of Smeds. Only polymers, in this case modified alginate or hyaluronic acid polymers, are reacting with each other via the methacrylic groups. Thus, the reactions of Smeds are crosslinking reactions of already finished polymers, but do not belong to the reaction type of

polymerization.

Accordingly, Applicant respectfully asserts that amended claim 32 of the present invention patentably distinguishes over the Allen-Petit, in evidenced by Mallégol, and/or in view of Kashiwagi. Therefore, dependent claims 33-36, 38-41, 45-48, 58-60 and new dependent claim 71 are patentably distinguishes over the prior references, either in combination or alone, for the reasons noted above, as well as for the additional features recited therein.

According, reconsideration and withdrawn of these 102 and 103 rejections are respectfully requested.

CONCLUSION

For at least the foregoing reasons, it is believed that all the pending claims of the present application patently define over the prior art and are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

Respectfully submitted,
J.C. PATENTS

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4 Venture, Suite 250
Irvine, CA 92618
Tel.: (949) 660-0761
Fax: (949)-660-0809

/JIAWEI HUANG/
Jiawei Huang
Registration No. 43,330